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PATENT

Attorney Docket No: 3495-0008-09

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	)	
	)	
Marc ALIZON et al.	)	Group Art Unit: 1641
	)	
Serial No.: 08/466,921	)	Examiner: J. PARKIN
	)	
Filed: June 6, 1995	)	
	)	
For: HIV-1 DNA FRAGMENTS THAT HYBRIDIZE TO GENOMIC HIV-1 DNA (As Amended)	)	

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

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APPELLANTS' BRIEF IN SUPPORT OF APPEAL

This is Appellants' brief on appeal from the final rejection of claims 62-73.

I. Real Parties in Interest

The real parties in interest are the assignees, Institut Pasteur and Centre National De La Recherche Scientifique, both of Paris, France, by virtue of a recorded assignment from the Appellants.

II. Related Appeals and Interferences

There are currently no other appeals and no interferences known to the Appellants, the undersigned, or the assignees that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

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III. Status of Claims

The application as filed contained claims 1-22, all of which were canceled. Claims 23-73 were added during prosecution. Of these claims, claims 23-38 and 53-59 were subsequently canceled; claims 39-52, 60, and 61 were allowed; and claims 62-73 were finally rejected. Appellants filed a Notice of Appeal from the final rejection of claims 62-73.

A copy of allowed claims 39-52, 60, and 61 and rejected claims 62-73 can be found in the Appendix.

IV. Status of Amendments

Appellants filed an Amendment after final on February 25, 2000, amending the Title of the application. In the March 20, 2000, Advisory Action (Paper No. 33), the Examiner indicated that this Amendment would be entered and that claims 62-73 were finally rejected.

V. Summary of the Invention

Appellants' invention relates to the discovery and cloning of DNA sequences of the genome of Human Immunodeficiency Virus Type 1 (HIV-1) that hybridize to genomic DNA of HIV-1. The appealed claims are directed to HIV-1 DNA fragments that hybridize to genomic DNA of HIV-1.

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HIV-1 was known at the time this application was filed. (Specification at 1, lines 9-13 and 23-29). Little was known, however, about the molecular biology of the virus. For example, the location of restriction sites within the viral genome was unknown. The lack of molecular clones of HIV-1 made analysis of the structural and regulatory components of HIV-1 difficult.

Against this backdrop of uncertainty, Appellants were the first to create cDNA clones of HIV-1, which they designated pLAV 13, pLAV 17, and pLAV 82. (*Id.* at 7, lines 9-15). These clones contained HIV-1 fragments of 2.5 kb, 0.6 kb, and 0.8 kb, respectively. (*Id.*) Appellants amplified these clones and cross-hybridized their HIV-1 fragments. (*Id.*) Appellants generated restriction fragments by cleavage of these HIV-1 fragments with *PstI, Hind*III, *Sac*I, *Bgl*II, *Kpn*I, *Xho*I, and *BamHI* and created restriction maps of these fragments. (*Id.* at Fig. 1.) A probe generated by nick-translation of pLAV 13 was used as a probe to detect DNA in Southern blots of HIV-1 infected lymphocytes. (*Id.* at 7-8.)

This probe was also used as a probe to identify seven molecular clones of HIV-1 genomic DNA. In this way, Appellants were the first to create recombinant molecular clones of genomic HIV-1 DNA, which they designated λ-J19, λ-J81, λ-J27, λ-J31, and

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λ-J57.[1] (*Id.* at 9-10.) Appellants generated restriction fragments by cleavage of these HIV-1 clones with *Hind*III and determined that all of these clones had the same *Hind*III sites, except for an additional *Hind*III site in λ-J81 at approximately 5,550. (*Id.* at 9-10 and Fig. 1.) Appellants generated restriction fragments by cleavage of λ-J19 with *Hind*III, *Sac*I, *BamH*I, *Pst*I, *Bgl*II, *Kpn*I, *Eco*RI, *Xho*I, and *Sal*I and created a restriction map of λ-J19. (*Id.* at 4 and Fig. 2.)

Appellants performed Southern blotting of isolated restriction fragments of HIV-1 clones λ-J19 and λ-J81, as well as other viral clones. (*Id.* at 10-12.) Nick-translated, genomic molecular HIV-1 clone λ-J19 hybridized to all five *Hind*III fragments of λ-J81 under stringent hybridization and wash conditions. (*Id.* at 10-11, bridging paragraph.) Conversely, nick-translated HTLV-II DNA did not hybridize to *Hind*III fragments of λ-J81, λ-J19, or λ-J27 under low stringency conditions. (*Id.* at 11, paragraph 3.)[2] Furthermore, HIV-1

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[1] The λ-J19 and λ-J81 clones were deposited at the Collection Nationale des Cultures de Micro-organismes (C.N.C.M.), a depository for biological material maintained by Institut Pasteur in Paris, France. (*See* specification at 14, lines 23-27).

[2] HTLV-II is a human retrovirus with a tropism for OKT4 T cells. (*See* specification at 11, lines 8-10).

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genomic DNA did not cross-hybridize with Visna viral genomes or human endogenous viral genomes even under non-stringent conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C. (*Id.* at 12, paragraph 1). Appellants are claiming HIV-1 DNA fragments, which hybridize to the genomic DNA of HIV-1 under these conditions.

VI. Issues

Enablement of the claims on appeal is not an issue. Rather, Appellants' February 25, 2000, Amendment and Response to Paper No. 29 overcame the rejection of claims 62-73 under 35 U.S.C. § 112, first paragraph, for lacking enablement commensurate in scope with the claims. (*See* Paper No. 33 at 2.) The Examiner concedes that claims 62-73 are enabled. (*See id.*)

The first issue on appeal is whether the invention of claims 68 and 69 is sufficiently definite as required by 35 U.S.C. § 112, second paragraph.

The second issue on appeal is whether the invention of claims 62-73 is sufficiently described in Appellants' specification as required by 35 U.S.C. § 112, first paragraph.

VII. Grouping of Claims

For purposes of appeal, the Appellants have grouped the claims as follows:

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Concerning the appealed grounds of rejection of claims 68 and 69 for being indefinite, all claims stand or fall together.

Concerning the appealed grounds of rejection of claims 62-73 for lacking an adequate written description, the claims do not stand or fall together. Rather, as Appellants will explain in the arguments below, each of claims 62-73 stands or falls separately.

VIII. Argument

A. The Scope of Claims 68 and 69 Can Be Determined with a Reasonable Degree of Precision and Particularity

The Examiner concludes that the phrase "amplified copy" in claims 68 and 69 is vague and indefinite since the nature of the amplification is not provided. (Paper No. 29 at 2.) The Examiner questions whether the claims are directed towards PCR amplified HIV-1 fragments[3] or HIV-1 fragments amplified by some other process, such as amplification of a lambda phage clone containing an HIV-1 insert. (*Id.*) Appellants will conclusively show that the scope of claims 68 and 69 can be determined with a reasonable degree of precision and particularity.

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[3] Appellants claim a priority date of September 19, 1984. The later discovery of alternative processes for the amplification of DNA fragments is irrelevant to whether claims 68 and 69 fulfill 35 U.S.C. § 112, second paragraph.

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1. The Phrase "Amplified Copy" is Understood by the Skilled Artisan

Claims in an application must define the metes and bounds of the claimed invention with a reasonable degree of precision and particularity. *Ex parte Ohsumi*, 21 U.S.P.Q.2d 1020, 1024 (Bd. Pat. App. & Int. 1991). Appellants' use of the phrase "amplified copy" defines the metes and bounds of the claimed invention with a reasonable degree of precision and particularity because the skilled artisan understands the metes and bounds of this phrase.

The skilled artisan understands that the claimed HIV-1 fragment must be a copy and must be amplified. The skilled artisan understands that the claimed HIV-1 fragment is not limited to one generated by any particular amplification technique, but rather encompasses a copy of the claimed DNA fragment of HIV-1, where the copy has been further copied by the skilled artisan to generate additional copies.

It is clear that the skilled artisan, upon reading Appellant's claims 68 and 69, would not be confused as to what these claims encompass. Accordingly, the use of the phrase "amplified copies" in claims 68 and 69 does not render these claims vague and indefinite under 35 U.S.C. § 112, second paragraph. *See Ex parte Ohsumi*, 21 U.S.P.Q.2d at 1024. The

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rejection of claims 68 and 69 under 35 U.S.C. § 112, second paragraph, should be reversed.

2. Breadth is Not Indefiniteness

Breadth is not indefiniteness. *In re Gardner*, 427 F.2d 786, 166 U.S.P.Q. 138 (C.C.P.A. 1970). Consequently, the fact that Appellants' claims encompass amplified copies of HIV-1 DNA fragments made by the skilled artisan using any amplification process cannot make Appellants' claims indefinite. The Examiner's basis for this rejection is in error. This is another reason that the rejection of claims 68 and 69 under 35 U.S.C. § 112, second paragraph, should be reversed.

B. Appellants Had Possession of the Claimed Invention

The Examiner concludes that "the skilled artisan, upon perusal of the specification, would not reach the conclusion that applicants contemplated isolating and purifying other HIV-1 fragments that hybridize under the precise conditions claimed." (Paper No. 29 at 3.) The Office concedes that the specification describes the claimed hybridization conditions. (Paper No. 29 at 2-3.) However, it is the Examiner's belief that the claimed hybridization conditions were described in the specification in reference to a hybridization assay with HIV-1 clones, but for a different purpose. (*Id.* at 3.) The Examiner further believes

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that the specification does not describe hybridization assays involving λJ19 restriction fragments and any other HIV-1 clones; fails to describe any other nucleic acids with the exception of λJ19, λ27, and λ81 restriction fragments; and does not provide any restriction maps or nucleotide sequences of any other HIV-1 isolate. (*Id.*) The Office also alleges that the specification fails to describe the preparation of amplified DNA fragments. (*Id.*)

Appellants will show that each assertion is erroneous.

1. Appellants Had Possession of Hybridization Conditions of 20% Formamide, 8xSSC, at 37°C, with Washes in 2xSSC, 0.1%SDS, at 37°C for Hybridizing to HIV-1 Genomic DNA

Appellants invention relates to DNA sequences **hybridizable** to genomic HIV-1 DNA. (Specification at 1, lines 1-3.) The DNAs according to the invention include DNA **fragments**. (*Id.* at 2, lines 20-24.) Appellants contemplated making and using many different fragments of HIV-1 DNA that would hybridize to genomic HIV-1 DNA.

Hybridization experiments indicated that all five *Hind*III fragments of λJ81 hybridized to λJ19 DNA under stringent hybridization and wash conditions. (*Id.* at 10-11, bridging paragraph.) Thus, it cannot be disputed that Appellants had possession of HIV-1 fragments that hybridize to HIV-1 genomic

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DNA under stringent conditions. Furthermore, it cannot be disputed that these fragments encompass the entire genome of HIV-1. It is, therefore, clear that Appellants contemplated making and using various fragments of HIV-1, which encompass the entire genome of HIV-1 and that hybridize to genomic HIV-1 DNA.

Appellants did not describe DNA sequences hybridizable to genomic HIV-1 DNA under only one particular hybridization condition, but described a variety of hybridization conditions for use with genomic HIV-1 DNA. To be certain, Appellants described stringent conditions for hybridizing nick-translated λ-J19 to all five *Hind*III fragments of λ-J81. (*Id.* at 10-11, bridging paragraph.) However, Appellants also described other hybridization conditions. For example, nick-translated HTLV-II DNA did not hybridize to *Hind*III fragments of λ-J81, λ-J19, or λ-J27 under low stringency conditions. (*Id.* at 11, paragraph 3.) Furthermore, HIV-1 genomic DNA did not cross-hybridize with Visna viral genomes or human endogenous viral genomes even under non-stringent conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C. (*Id.* at 12, paragraph 1). There can be no doubt that these non-stringent conditions were for hybridization with HIV-1 genomic DNA.

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There can be no doubt that these conditions are a species of hybridization conditions under which HIV-1 DNA fragments would be "hybidizable" to HIV-1 genomic DNA. Since the specification discloses both the genus (hybridizable), and a species within this genus (conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C), the skilled artisan would have no doubt that Appellants were in possession of fragments hybridizable under the claimed conditions. The skilled artisan would immediately recognize that Appellants contemplated that these conditions are a species of the invention.

Furthermore, the burden is on the Office to show why the skilled artisan would not recognize a description of Appellants' claimed invention in the specification. *See In re Wertheim*, 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 (C.C.P.A. 1976). The Office has not fulfilled this burden since the Office has given no reasons why the skilled artisan would not consider the claimed species of hybridization conditions to be within the described genus, *i.e.*, hybridizable to HIV-1 genomic DNA.[4] *See id.* The

[4] In Paper No 29, the Examiner stated that Appellants have not met their burden, citing *Bigham v. Godtfredsen*. Unlike the situation in *Bigham*, Appellants are not attempting to add description of a new species within a previously disclosed genus. Rather, as apparently recognized by the (continued...)

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Examiner's simple statement that the purpose of this hybridization assay was slightly different does not fulfill this burden because it does not provide these reasons.

The recitation "wherein the fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C" in claims 62, 64, 66, 68, 70, and 72 is fully supported by the specification. Appellants actually used the claimed conditions for hybridizing to genomic HIV-1 DNA. There can be no doubt that Appellants had possession of the claimed conditions for hybridizing to genomic HIV-1 DNA.

2. Appellants Had Possession of HIV-1 Genomic Molecular Clone λJ19

Appellants deposited two genomic HIV-1 clones, λJ19 and λJ81. (*Id.* at 14, lines 23-27.) It is undisputed that Appellants had possession of these molecular clones and that these clones encompass the entire HIV-1 genome.

Hybridization experiments indicated that all five *Hind*III fragments of λJ81 hybridized to λJ19 DNA under stringent hybridization and wash conditions. Genomic molecular clones

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[4](...continued)
Office, the claimed hybridization conditions are fully disclosed in the specification. Consequently, *Bigham* is irrelevant to the issues on appeal.

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λJ81 an λJ19 are full-length molecular clones of HIV-1. (*See* Fig. 2.) Since all fragments of λJ81 hybridized to λJ19 DNA, there can be no doubt that Appellants contemplated using genomic molecular clone λJ19 as a probe for hybridizing to HIV-1 fragments representing all different parts of the HIV-1 genome. Surely, the actual use of fragments representing all different parts of the HIV-1 genome would convey this fact to the skilled artisan. Appellants actually hybridized λJ19 to HIV-1 DNA fragments encompassing the entire HIV-1 genome. Claims 63, 65, 67, 69, 71, and 73 are fully supported by the specification.

3. Appellants Had Possession of HIV-1 Restriction Fragments Encompassing the Entire HIV-1 Genome

As described above, it cannot be disputed that Appellants had possession of molecular clones of the entire HIV-1 genome. Appellants generated restriction fragments by digesting these clones with restriction enzymes. The digests were used to create restriction maps of λJ19 and λJ81. (*Id.* at 4 and Fig. 2.) The restriction maps were oriented by hybridizing blots of these clones with an HIV-1 DNA probe. (*Id.* at 10, lines 4-5.) It cannot be disputed that Appellants had possession of all of the restriction fragments illustrated by the restriction maps of Fig. 2. Likewise, it cannot be disputed that Appellants had possession of all of the restriction fragments illustrated by

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the restriction maps of Fig. 1. Thus, Appellants had possession of HIV-1 restriction fragments encompassing the entire HIV-1 genome.

The recitation "A purified DNA fragment of HIV-1 consisting of a restriction fragment" in claim 62, and dependent claim 63, is fully supported by the specification. The rejection of claims 62 and 63 under 35 U.S.C. § 112, first paragraph, should be reversed.

4. Appellants Had Possession of Cloned HIV-1 DNA Fragments Encompassing the Entire HIV-1 Genome

As described above, Appellants deposited two genomic HIV-1 clones, λJ19 and λJ81. It is undisputed that λJ19 and λJ81 contain cloned HIV-1 DNA fragments encompassing the entire HIV-1 genome. Thus, Appellants had possession of cloned HIV-1 DNA fragments encompassing the entire HIV-1 genome.

The recitation "A cloned DNA fragment of HIV-1" in claim 64, and dependent claim 65, is fully supported by the specification. The rejection of claims 64 and 65 under 35 U.S.C. § 112, first paragraph, should be reversed.

5. Appellants Had Possession of Double-Stranded HIV-1 DNA Fragments Encompassing the Entire HIV-1 Genome

As described above, Appellants deposited two genomic HIV-1 clones, λJ19 and λJ81. It cannot be disputed that λJ19 and λJ81

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contain double-stranded HIV-1 DNA fragments encompassing the entire HIV-1 genome. Thus, Appellants had possession of double-stranded HIV-1 DNA fragments encompassing the entire HIV-1 genome.

As further described above, Appellants generated restriction fragments by digesting λJ19 with restriction enzymes. These fragments comprise isolated double-stranded HIV-1 DNA.

The recitation "An isolated double-stranded DNA fragment of HIV-1" in claim 66, and dependent claim 67, is fully supported by the specification. The rejection of claims 66 and 67 under 35 U.S.C. § 112, first paragraph, should be reversed.

6. Appellants Had Possession of Amplified Copies of HIV-1 DNA Fragments Encompassing the Entire HIV-1 Genome

Appellants ligated HIV-1 genomic DNA to lambda phage DNA, λ-L47.1. (Specification at 8-9.) After *in vitro* packaging of the recombinant DNA, the recombinant phage were plated out on a bacterial host. (*Id.*) The bacterial host generated amplified copies of HIV-1 genomic DNA fragments ligated to the λ-phage DNA. Appellants had possession of these amplified copies. The HIV-1 DNA fragments so amplified encompass the entire HIV-1 genome. (*Id.* at 9, paragraph 2.)

The specification states:

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> The invention also relates more specifically to cloned probes which can be made starting from any DNA fragment according to the invention, thus to recombinant DNAs containing such **fragments**, particularly any plasmid **amplifiable** in procaryotic or eukaryotic cells and carrying said fragments.

(*Id.* at 12, paragraph 2, emphasis added.) Having read this passage from the specification, the skilled artisan would have no doubt that Appellants contemplated making and using amplified copies of HIV-1 DNA fragments.

The recitation "An amplified copy of a DNA fragment of HIV-1" in claim 68, and dependent claim 69, is fully supported by the specification. The rejection of claims 68 and 69 under 35 U.S.C. § 112, first paragraph, should be reversed.

7. Appellants Had Possession of Vectors Comprising HIV-1 DNA Fragments Encompassing the Entire HIV-1 Genome

As described above, Appellants deposited two genomic HIV-1 clones, λJ19 and λJ81. It is undisputed that λJ19 and λJ81 are lambda phage vectors that contain cloned HIV-1 DNA fragments encompassing the entire HIV-1 genome.

The recitation "A vector comprising an HIV-1 DNA fragment" in claim 70, and dependent claim 71, is fully supported by the specification. The rejection of claims 70 and 71 under 35 U.S.C. § 112, first paragraph, should be reversed.

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8. Appellants Had Possession of Host Cells Transformed with Vectors Comprising HIV-1 DNA Fragments Encompassing the Entire HIV-1 Genome

Appellants propagated the lambda vectors containing HIV-1 genomic DNA, *e.g.* λJ19, in bacterial hosts. (Specification at 8-9.) There can be no doubt that Appellants had possession of host cells transformed with vectors comprising HIV-1 DNA fragments encompassing the entire HIV-1 genome.

The recitation "A host cell transformed with a vector comprising an HIV-1 DNA fragment" in claim 72, and dependent claim 73, is fully supported by the specification. The rejection of claims 72 and 73 under 35 U.S.C. § 112, first paragraph, should be reversed.

9. Appellants Do Not Need to Provide Restriction Maps or Nucleotide Sequences from Any Other HIV-1 Isolate to Provide an Adequate Written Description of the Claimed HIV-1 Fragments

The written description requirement of 35 U.S.C. § 112, first paragraph, is not violated just because a claim is broader than the specific embodiment disclosed in a specification. *See In re Rasmussen*, 650 F.2d 1212, 1214, 211 U.S.P.Q. 323, 326-27 (C.C.P.A. 1981). Every species in a genus need not be described in order for a genus to meet the written description requirement. *See Utter v. Hiraga*, 845 F.2d 993, 998-99, 6 U.S.P.Q.2d 1709, 1724 (Fed. Cir. 1988). Rather, a description

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of a genus may be achieved by means of a recitation of a representative number of species falling within that genus. *See Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997).

Appellants describe cloning HIV-1 fragments and genomic DNA. (Specification at 5-11). Appellants describe that λJ19 and λJ81 are genomic clones of HIV-1 DNA. (*Id.* at 9-11.) Appellants describe that all of the *Hind*III restriction fragments of λJ81 DNA hybridize under stringent hybridization and washing conditions to λJ19 DNA. (*Id.* at 11, paragraph 1.) Therefore, the skilled artisan would recognize that Appellants' invention encompasses HIV-1 DNA fragments that hybridize to HIV-1 genomic DNA.

Furthermore, Appellants provide restriction maps of the entire HIV-1 genome. (*Id.* at 4 and Figs. 1 and 2). The restriction maps provided in Figs. 1 and 2 must be considered part of Appellants' written description. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 U.S.P.Q.2d 1111, 1118 (Fed. Cir. 1991). Consequently, the skilled artisan would recognize that Appellants had possession of all of the HIV-1 restriction fragments depicted in Figs. 1 and 2.

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In Figs. 1 and 2, Appellants describe a genus of HIV-1 fragments, which would be expected to hybridize to HIV-1 genomic DNA under the claimed conditions. The skilled artisan would further recognize that the HIV-1 restriction fragments depicted in Figs. 1 and 2 were representative of a genus of HIV-1 DNA fragments that hybridize to HIV-1 genomic DNA under the claimed conditions. Since Appellants describe a representative number of species falling within the genus of HIV-1 fragments that hybridize to HIV-1 genomic DNA, Appellants' specification provides an adequate written description of the claimed HIV-1 fragments. *See Eli Lilly*, 119 F.3d at 1566, 43 U.S.P.Q.2d at 1404. The rejection of claims 62-73 under 35 U.S.C. § 112, first paragraph, should be reversed for this additional reason.

IX. Conclusion

The rejection of claims 68 and 69 under 35 U.S.C. § 112, second paragraph, on the ground of being vague and indefinite is in error. The rejection of claims 62-73 under 35 U.S.C. § 112, first paragraph, on the ground of lack of an adequate written description is in error. Reversal of the rejections is respectfully requested.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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